K032956

OCT 1 0 2003

510(k) SUMMARY
AccuSonic A-Scan

Applicant:	Accutome Inc.
Address:	263 Great Valley Parkway Malvern, PA 19355
Contact Person:	Jeffrey L. Wright Manager, Engineering, Manufacturing & QC
Telephone:	(610) 889-0200 (610) 889-3233 fax
Preparation Date:	August 25, 2003
Device Name:	AccuSonic A-Scan
Common Name:	Biometer
Classification:	System, Imaging, Pulsed Echo, Ultrasonic (see: 21 CFR 892.1560) Product Code: IYO Panel: 90
Legally Marketed Predicate Devices:	Accutome Advent AB (K960765) previously by Mentor Ophthalmics and acquired by Accutome in December of 1999. (However, the AccuSonic A-Scan does not function as a B-Scan.); Teknar Ophthasonic A-Scan (K860757); Teknar Opthasonic A/P III (K903666); DGH 3000A A-Scan (K872726); DGH 4000 A-Scan/Pach (K913067)
Description of the Device:	The AccuSonic A-Scan device is designed as a biometer, which uses pulsed echo ultrasound to measure the axial length, and the location of other structures of the eye. It utilizes an eye-contact probe to generate and receive the ultrasound pulses, and provides a one-dimensional display of returning pulse echoes, with positive peaks to indicate the location of ocular structures. The distance between peaks can be measured.
Indications for Use:	The instrument is used for measuring the axial length, anterior chamber depth and lens thickness of the eye. It is also used for calculating the optical power of the IOL to be implanted during cataract surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2003

Mr. Jeffrey L. Wright
Manager, Engineering, Manufacturing & QC
Accutome, Inc.
263 Great Valley Parkway
MALVERN PA 19355

Re: K032956
Trade Name: AccuSonic A-Scan
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: 90 IYO
Dated: August 25, 2003
Received: September 22, 2003

Dear Mr. Wright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducer intended for use with the AccuSonic A-Scan, as described in your premarket notification:

Transducer Model Number

A-mode 10 MHz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

AccuSonic A-Scan
510(k) Notification

4.3 Indications for Use

510(k) Number (if known): K032956

Device Name: Accusonic A-Scan

Indications for Use:

The instrument is used for measuring the axial length, anterior chamber depth and lens thickness of the eye. It also is used for calculating the optical power of the IOL to be implanted during cataract surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use_____

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032956

AccuSonic A-Scan
510(k) Notification

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	N									
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

System includes A-Mode 10 MHz Transducer.

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032956